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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/806,253	03/22/2004	David C. Baulcombe	616292000110	1920

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EXAMINER	
BOWMAN, AMY HUDSON	
ART UNIT	PAPER NUMBER
1635	

MAIL DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/806,253	BAULCOMBE ET AL.	
	Examiner	Art Unit	
	AMY BOWMAN	1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 February 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *32-37,39-41,49 and 66* is/are pending in the application.

4a) Of the above claim(s) *33,34,39 and 40* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *32,35-37,41,49 and 66* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☒ Certified copies of the priority documents have been received in Application No. 09/491,549.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 1/5/09 has been entered.

Claims 32-37, 39-41, 49, 66 and 67 are pending. Claims 33, 34, 39, and 40, as well as the subject matter of claim 32 that is not directed to mammal, is withdrawn from consideration as being directed to non-elected subject matter. Claims 32, 35, 36, 37, 41, 49, 66, and 67 are under examination.

Applicant's amendments and/or arguments filed 1/5/09, with respect to the rejection(s) of record have been fully considered and are persuasive. Therefore, these rejections have been withdrawn. However, upon further consideration, a new ground of rejection is applied as set forth below.

New Objections/Rejections

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 32, 35-37, 41, 49, 66, and 67 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. THIS IS A NEW MATTER REJECTION.

Claim 32 is directed to a method of detecting PTGS of a target gene in a mammal comprising detecting the presence of SRMs in an organism "suspected that PTGS is occurring".

The specification does not contemplate a limitation wherein the process is performed in an extract prepared from a mammal "suspected that PTGS is occurring".

Claims 35-37, 41, 49, 66, and 67 are rejected because they depend from claim 32. The instant specification does not set forth a step of suspecting that PTGS is occurring, followed by actually detecting the presence of SRMs in the cellular extract.

MPEP §2163.06 notes:

> If new matter is added to the claims, the examiner should reject the claims under 35 U.S.C. 112, first paragraph - written description requirement. In re Rasmussen, 650 F.2d 1212, 211 USPQ 323 (CCPA 1981).

MPEP §2163.02 teaches that:

> Whenever the issue arises, the fundamental factual inquiry is whether a claim defines an invention that is clearly conveyed to those skilled in the art at the time the application was filed...If a claim is amended to include subject matter, limitations, or terminology not present in the application as filed, involving a departure from, addition to, or deletion from the disclosure of the application as filed, the examiner should conclude that the claimed subject matter is not described in that application.

A review of the specification does not reveal support for where the claim amendments are found. Should applicant disagree, applicants are encouraged to point out with particularity by page and line number where such support might exist for each claim limitation added in the amended claims filed on 5/9/08.

There is no support for this claim limitation in the claimed priority documents. Therefore, the effective filing date of the instant claims is considered, for purposes of prior art, to be 3/22/04, which is the filing date of the instant application.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 32, 35-37, 41, 49, 66, and 67 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the specific examples of the specification regarding PTGS detection, does not reasonably provide enablement for a method of detecting PTGS of any target gene in any mammal via the detection of any SRM with any degree of identity or similarity with the target gene. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

Factors to be considered in a determination of lack of enablement include, but are not limited to:

(A) The breadth of the claims;

(B) The nature of the invention;

(C) The state of the prior art;

(D) The level of one of ordinary skill;

(E) The level of predictability in the art;

(F) The amount of direction provided by the inventor;

(G) The existence of working examples; and

(H) The quantity of experimentation needed to make or use the invention based on the content of the disclosure.

In re Wands, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988)

The instant claims are drawn to a method of detecting PTGS of a target gene in a mammal comprising detecting the presence of SRMs which are 20-30 nucleotides in length (SARM, SRM, or both) and determining any degree and type of similarity or identity between the SRM and the target. Applicant has not drawn a nexus between detection of such a broad genus of molecules with the actual detection of PTGS.

The specification does not adequately demonstrate that detection of any SRM (SARM, SRM, or both) with any type and degree of similarity with any mammalian target would in fact result in detection of PTGS.

For example, Elbashir et al. (The EMBO Journal, 2001, 20(23), pages 6877-6888, of record and cited on the IDS filed on 7/20/07) teaches that the target recognition process of siRNA molecules is highly sequence specific, but not all positions of the siRNA contribute equally to the target recognition; mismatches in the center of the siRNA duplex prevented target RNA cleavage. Furthermore, Elbashir et al. teach that siRNA molecules are double-stranded molecules 21-23 nucleotides in length and are the sequence-specific mediators of RNAi and PTGS (see abstract).

Therefore, it is established in the art that mismatches alter the activity of duplexed inhibitory dsRNA molecules and that it is duplexes of sense and antisense 21-23 nt in length RNA molecules that are the mediators of PTGS. However, the instant claims do not require detection of both SARMs and SRMs and do not require for the molecules to be duplexed. Since the instant molecules are not necessarily in a duplex form, it is unlikely that SRMs (SARMs, SRMs, or both) with a minimal level of "identity" or "similarity" with a mammalian target would in fact be predictors of PTGS. Therefore, the specification has not overcome the unpredictability of activity of sequence specific inhibitory molecules without reasonable specificity to the target; and has not demonstrated that detection of the instant genus of possible molecules would in fact be indicative of PTGS and is therefore not enabled over the instant claim scope.

Furthermore, claim 32 clearly does not require the presence of SARMs and SRMs, as evidenced by dependent claims 36, 37, and 67. Although the specification sets forth examples wherein SARMs approximately 25 nucleotides in length were detected in cells that PTGS was occurring, the specification does not demonstrate that the detection of SRMs alone; or detection of SARMs and SRMs with no necessary relationship with each other would in fact be indicative of PTGS of any mammalian target gene.

In fact, the instant specification does not demonstrate detection of SARMs, SRMs, or SARMS and SRMs specific for any mammalian gene with a correlation of PTGS but rather demonstrates detection of specific 25 nt SARMs in plants and hypothesizes that PTGS could occur in mammals that ingest the plant material.

Furthermore, the instant specification discloses "The precise role of 25 nt RNA in PTGS remains to be determined conclusively. However, as they are long enough to convey sequence specificity yet small enough to move through the plasmodesmata, it is probable that they are components of the systemic signal and specificity determinants of PTGS." (see page 27). Therefore, the specification sets forth that the role of the specific 25 nt SARMs that were detected in plants undergoing PTGS has not been determined and hypothesizes that such RNA molecules may be specificity determinants of PTGS. The teachings of the specification are not enabling for a broad method of detecting PTGS with such a broad genus of molecules that have not been associated with the presence of PTGS with regards to any mammalian target, wherein the claims read on the detection of any sense or antisense 20-30 mer degradation product, which would not be indicative of PTGS, and wherein the SARMs (SRMs, SARMs, or both) have any level and type of identity or similarity with the target gene.

Given the teachings of the specification as discussed above, one skilled in the art could not predict *a priori* whether detection of any SARM (SRM alone, SARM alone, or both without any specific relationship to each other) would in fact indicate PTGS of any mammalian gene. To practice the claimed invention, one of skill in the art would have to *de novo* determine which SARMs with what type and level of identity or similarity to the target gene would in fact act as determinants for PTGS within the instant method. Without further guidance, one of skill in the art would have to practice a substantial amount of trial and error experimentation, an amount considered undue and not routine, to practice the instantly claimed invention.

A conclusion of lack of enablement means that, based on the evidence regarding each of the above factors, the specification, **at the time the application was filed**, would not have taught one skilled in the art how to make and/or use the **full scope** of the claimed invention without undue experimentation (see MPEP 2164.01(a)).

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to AMY BOWMAN whose telephone number is (571)272-0755. The examiner can normally be reached on Monday-Thursday 6:00 - 4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James (Doug) Schultz can be reached on (571) 272-0763. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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